Medical documentation and electronic medical documentation

(Dokumentacja medyczna oraz elektroniczna dokumentacja medyczna)

J Wypyszewska [1,A,D], A Romaszewski [1,F,C], Z Kopański [1,2,E], M Głowacka [2,B], M Mazurek [3,B], J Rowiński [3,B,C], W Ptak [3,B]

Abstract – The authors presented the characteristics of documentation, including medical documentation. They drew attention to the basic elements that it should contain - data allowing identification of the entity, the employee providing benefits, numbering entries in chronological order, surname, first name and the patient's PESEL number (mother's PESEL number in the case of a newborn child or number and type of identity document, when the PESEL number has not been assigned), as well as the date of making individual entries. The importance of legal acts obliging each entity to readable and chronological complete data contained in medical records is underlined. The making of entries must take place immediately after providing the patient with the benefit. In addition, every person who makes an entry is required to label it with his or her name. No information contained in the documentation can be removed from it. The features of electronic medical records were also discussed. It was emphasized that nowadays it is the whole of documents (made in an electronic version) certified by Profil Zaufany ePUAP (ePUAP Trusted Profile), qualified electronic signature or a free system offered by ZUS.

Key words **-** medical documentation, electronic medical documentation.

Streszczenie – Autorzy przedstawili cechy charakterystyczne dokumentacji, w tym dokumentacji medycznej. Zwrócili uwagę na podstawowe elementy jakie winna zawierać, a więc dane pozwalające na identyfikację podmiotu, pracownika udzielającego świadczenia, numerację wpisów w porządku chronologicznym, nazwisko, imię, a także numer PESEL chorego (numer PESEL matki w przypadku noworodka albo numer oraz rodzaj dokumentu tożsamości, gdy numer PESEL nie został nadany), a także daty dokonania poszczególnych wpisów. Podkreślono, znaczenie aktów prawnych zobowiązujących każdy podmiot do czytelnego oraz chronologicznego uzupełniania danych zawartych w dokumentacji medycznej. Dokonywanie wpisów odbywać się musi niezwłocznie po udzieleniu pacjentowi świadczenia. Ponadto, każda osoba dokonująca wpisu zobligowana jest do opatrzenia go swoim oznaczeniem. Żadna informacja zawarta w dokumentacji nie może zostać z niej usunięta. Omówiono także cechy elektronicznej dokumentacji medycznej.
Podkreślono, że współcześnie jest to całość dokumentów (sporządzonych w wersji elektronicznej) poświadczonych przez Profil Zaufany ePUAP, kwalifikowany podpis elektroniczny albo bezpłatny system oferowany przez ZUS.

Słowa kluczowe **-** dokumentacja medyczna, elektroniczna dokumentacja medyczna.

Author Affiliations:

1. Faculty of Health Sciences, Collegium Medicum, Jagiel-lonian University
2. Laboratory of Clinical Skills and Medical Simulation, Ludwik Rydygier Collegium Medicum in Bydgoszcz Nocolaus Copernicus University in Toruń, Poland
3. Collegium Masoviense – College of Health Sciences, Żyrardów

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B. Gathering and listing data
C. The data analysis and interpretation
D. Writing the article
E. Critical review of the article
F. Final approval of the article

Correspondence to:

Prof. Zbigniew Kopański MD PhD, Faculty of Health Sciences, Collegium Medicum, Jagiel-lonian University, P. Michałowskiego 12 Str., PL- 31-126 Kraków, Poland, e-mail: zkopanski@o2.pl

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I. INTRODUCTION

In order for the documentation to be considered as medical, it must at least have the data allowing identification of the patient (name and surname, gender, date of birth, address, PESEL number or address, name and surname of his/her representative, if the patient is a minor, can not express the conscious consent or is incapacitated person). The documentation must also contain data allowing the identification of the entity and its organizational part in which the given benefit was granted. In addition, it should also include information characterizing the patient's condition, services provided to her/him and the date of producing individual documents. All medical certificates and opinions issued by a doctor are also included in the documentation [1,2].

Medical documentation can be divided into consolidated and individual [3]. Consolidated documentation is prepared for specific groups of patients. One can count among it, among others, admission book kept in a hospital or book containing nursing reports [1]. Consolidated documentation must contain data allowing identification of the entity, the employee providing benefits, numbering of entries in chronological order, surname, first name, and the patient's PESEL number (mother's PESEL number in the case of a newborn or number and type of identity document when the PESEL number has not been assigned) as well as the dates of making individual entries [3].

Individual documentation is prepared separately for individual patients [1]. You can divide it into the internal and the external. External individual documentation is prepared in order to meet the needs of patients using the services provided by the entity [1]. It includes, above all, all types of referrals (for examinations, consultations, treatment, etc.), opinions, medical certificate and report, vaccination and health records, as well as pregnancy records and a card informing about the course of hospital treatment [3]. Internal individual documentation is prepared to meet the needs of the entity providing health services [1]. The internal documentation includes, first of all, individual care cards (run by nurses or midwives), newborn cards, stories: diseases and health and diseases, immunization cards, as well as cards containing data obtained from background and family survey [3,4]. Internal individual medical documentation is usually supplemented by additional documents (eg patient's declarations authorizing another person to inspect medical records, obtain information about a patient's health condition and consent to provide services, as well as descriptions of tests done elsewhere), which can not be removed from it [22]. If the patient does not submit the second of these statements, attach an appropriate annotation to the documents [3,5].

If the patient is referred for treatment, consultation or examination, the managing entity is obliged to provide the other entity with necessary information from the internal individual patient documentation. The facility in which the patient has been consulted, or in which the examination has been performed, is obliged to make the results available for the managing entity [3-5].

External individual documentation is made available to the patient, which is confirmed by an appropriate entry in the internal individual documentation [3].

Pursuant to the Regulation, individual documentation prepared by each entity providing health-related services must contain data allowing identification of the entity, patient, employee providing the service or referring patients to another facility, the date of making individual entries, as well as complete data on the patient's state of health and the course of processes: diagnosis, therapy, rehabilitation and care. Data allowing to determine the entity is the name, departmental code and address of the place where the services were provided, while the data enabling identification of the employee providing the service include: name and surname, professional title, specializations, the right to practice and signature. The data informing about the health condition of a sick person includes, first of all, diagnoses of diseases, injuries, health problems or pregnancy, detailed descriptions of services received, recommendations, data on issued certificates, judgments and opinions, as well as information on prescriptions for medicines (including with dosing) and orders for supplying of a medical device [3,5,6].

The Regulation obliges each entity to read and chronologically complete the data contained in the medical documentation. Entries must be made immediately after providing the patient with a benefit. In addition, every person who makes an entry is required to label it with his or her name. No information contained in the documentation can be removed from it. If there is a need to correct the error, there is an obligation to delete an incorrect entry and to put an annotation informing about the reason for the error, the date of its occurrence and the designation of its author. All pages in the documentation prepared in paper version must be numbered chronologically. In addition, a patient designation must appear on the first page of the individual documentation. The remaining pages must contain at least the surname and name of the patient. If it is impossible to determine the patient's data, the entities are obliged to mark the documentation as "NN" and place an annotation informing about the reasons preventing identification of the patient's identity [3].

All data regarding diagnosed diseases, injuries and health problems must be prepared in accordance with the *International Statistical Classification of Diseases and Health Problems* (ICD-10). In each case, the statistical number and the name of the diagnosis should be provided. In the case of internal collective documentation kept in the form of a list containing information on prescriptions issued by a doctor, nurse or midwife (for yourself, spouse, siblings, lineal ascendants and descendants), it is possible to disregard the statistical number in the documentation. [3].

Medical documentation may be made in paper or electronic version [1,3].

II. MEDICAL DOCUMENTATION AND ELECTRONIC MEDICAL CUMENTATION

An electronic document is defined as a set of data ordered in a strictly defined way, which has been saved on an appropriate IT medium (device allowing to save, store and read data contained in it in a digital form) [7,8].

All documents (drawn up in an electronic version) certified by ePUAP Zaufany Profil (ePUAP Trusted Profile), a qualified electronic signature or a free system offered by the Social Insurance Institution[1] are defined as *electronic medical documentation*. These documents allow you to obtain a specific type of health-related services (excluding orders issued for the supply of medical devices) [7]. According to the definition, documents containing medical data are considered part of the electronic documentation only if they are stored on a data carrier [9].

The condition for keeping the documentation in the electronic version is the use of a teleinformatic system that secures documents not only against data loss and damage, but also features the functionality of their printing process. In addition, this system must ensure the integrity of the entered data and, at the same time, of the content of documents by protecting them against unauthorized changes. The system must also ensure continued access of authorized persons to the data, at the same time protecting them against access of persons without appropriate rights. All entries made in documents must contain data allowing identification of both their authors and employees providing service. In addition, each type of document must have appropriate information features. The key feature of the system, however, is the need to provide the possibility of sharing the documentation (or a part of it) in the same format in which it is processed (e.g. PDF or XML) [3,10]. In the case of the need to change the system, the transferred documentation must be supplemented with data informing about the exact date of transfer and the system from which it was obtained [3].

If the electronically prepared documentation is to be supplemented with other documents (e.g. radiological images or documentation made in paper version), the entity is obliged to designate a person whose task will be to digitally reproduce the data and place it in the ICT system so that it is clear and consistent whole [3].

Digital documentation (prepared in accordance with the provisions of *Polish Standards* defining the principles of data storage and exchange in the health sector, developed on the basis of European standards) is perpetuated through the use of appropriate technical solutions to ensure the collection of documents, credibility and the ability to use the data contained therein at least in the period in which this documentation must be kept [3,9,10]. Documents prepared in an electronic version are considered to be secured in the case of uninterrupted access to data contained in them only for authorized persons, protection of documents from destruction and the use of generally recognized as effective methods of document protection. In order to provide effective protection for electronic documents, it is first necessary to systematically analyze emerging or anticipated threats, develop and implement appropriate procedures to protect documents (regarding, in particular, conditions for its storage and sharing), and apply security methods appropriate to threats. In addition, ongoing control and assessment of the effectiveness of both organizational and technical-IT security methods should be carried out. Long-term document storage plans should also be drawn up and implemented, taking into account the need to change media or data formats to ensure continued access to documents [3,10].

III. BENEFITS FROM ELECTRONIC MEDICAL DOCUMENTATION

Preparation and provision of medical documentation in a digital version brings benefits not only for patients and medical personnel, but also for people managing the facilities that provide services, the payer and for the whole health system [11]. These include, first of all, the possibility of providing quick access for both sick people and specialists to all legible data characterizing the health condition of the recipient (regardless of the place where he receives the benefit). In the case of medical workers, this has

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a particular impact on the speed and efficiency of diagnosis and therapy processes [12,13].

An advantage resulting from the implementation of electronic documents, conditioned by the skills of medical staff is the reduction of the time necessary to enter the necessary data (in comparison to traditional documents) [12]. In addition, the improvement of the therapy process is facilitated by the use of ready-made procedures (e.g. using a displayed list of tests proposed for the patient after the specialist has entered the diagnosis). Thanks to this solution, the time saved can be used to examine the patient [11].

Documentation processed with the help of the ICT system guarantees the access of medical personnel to the latest information (provided that they are updated). In addition, medical documents in the digital version must be completed in a precisely defined, forced by the system way, which minimizes the risk of errors resulting, among others, from entering incomplete data. In the case of making any changes or entries in the document, the need to log in early guarantees access to the data of the user responsible for the modifications [11-13].

Digital data preparation facilitates not only their collection, processing, maintaining the durability and chronological nature of records, but also the possibility of exercising control and carrying out analysis, e.g. for statistical purposes. In addition, the processing of documents only in the electronic version involves a reduction of costs resulting from the need to archive data. The benefits of implementing such a solution can contribute to increasing the work efficiency of the staff [11].

Preparation of documents in the electronic version significantly facilitates their transmission between branches, regardless of their location [14]. For this reason, facilitating access to all data related to the provision of health services entails the possibility of implementing innovative solutions, which include among others telemedicine [11].

Medical documentation prepared in an electronic version is considered equivalent to the documentation produced in the written version [7].

IV. IDENTIFICATION OF THE USERS

Personal data are primarily used to determine the identity of people. Two types of identification can be distinguished: direct, in which the identity of a person is determined on the basis of the data characterizing her/him (including names, dates of birth or PESEL numbers) and indirect, in which the identification of a person is the result of inference regarding mutual relations between data or is based on information obtained from outside. An example of such a method of identification is face reconstruction based on images taken during diagnostic tests related to the results of previously performed procedures [6,15].

To determine the identity of users who prepare medical documentation in an electronic version should serve, among others electronic signatures: qualified or confirmed via Profil Zaufany ePUAP (Trusted ePUAP Profile) [7].

An electronic signature is defined as qualified in case of verification of its security by a valid certificate issued through the national certification center [25-27]. All data related to the submission of electronic signatures must be kept secret by all persons employed in the entity providing the so-called trust service and in all other entities cooperating with it. This order applies without any time limit. For the use of a qualified signature without the necessary qualifications, there are penalties: financial, restriction of liberty or deprivation of libery. A fine may also be imposed for not maintaining confidentiality of data by a person obliged to do so [16].

The second way to confirm electronic signatures is to use the ePUAP platform created to enable citizens to communicate with administrative institutions. One of the free services offered as part of this platform is the so-called Trusted profile allowing identification of the user of the account (confirmed by public entities) and certification of digital documents by her/him, not requiring her/him to use a paid qualified signature [4,8].

The result of submitting the electronic signature in the document (confirmed by the Trusted or qualified Profile) is to cause legal effects identical to those in the case of handwritten signatures. In the case of signatures recognized as qualified, this effect is valid only when the certificate verifying them is valid [16,17].

V. REFERENCES

[1] Liber A. Problemy anonimizacji dokumentów medycznych. Część 1. Wprowadzenie do anonimizacji danych medycznych. Zapewnienie ochrony danych wrażliwych metodami F(A) – I F(A,B) – anonimizacji. Puls Uczelni 2014; 8(1): 13-21.

[2] Ustawa z dnia 23 marca 2017 r. o zmianie ustawy o prawach pacjenta i Rzeczniku Praw Pacjenta oraz niektórych innych ustaw (j.t. Dz. U. 2017 poz. 836).

[3] Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2015 r. w sprawie rodzajów, zakresu i wzorów dokumentacji medycznej oraz sposobu jej przetwarzania (j. t. Dz. U. 2015 poz. 2069).

[4] Grudzińska-Kuna A, Papińska-Kacperek J. Usługi elektronicznej administracji dla obywateli w Polsce – wybrane aspekty. Rocz Kol Analiz Ekon 2012; 24: 119-131.

[5] Szymczyk D, Horoch A. Implementacja elektronicznej dokumentacji medycznej. Część 3 – szkolenie personelu medycz-

nego w zakresie technicznego i prawnego użytkowania danych sensytywnych. Med Ogólna Nauk Zdr 2013; 19(3): 331-336.
[6] Liber A. Problemy anonimizacji dokumentów medycznych. Część 2. Anonimizacja zaawansowana oraz sterowana przez posiadacza danych wrażliwych. Puls Uczelni 2014; 8(2): 13-24.
[7] Ustawa z dnia 28 kwietnia 2011 r. o systemie informacji w ochronie zdrowia (j.t. Dz. U. 2011 nr 113 poz. 657).
[8] Ustawa z dnia 17 lutego 2005 r. o informatyzacji działalności podmiotów realizujących zadania publiczne (j.t. Dz. U. 2005 Nr 64 poz. 565 z późn. zm.).
[9] Nyczaj K, Piecuch P. Elektroniczna dokumentacja medyczna. Warszawa; WIP, 2013.
[10] Strzelecka A. Technologie informacyjne i komunikacyjne istotnym elementem przepływu informacji w innowacyjnej działalności podmiotów leczniczych. Zesz Nauk Polit Częstochowa 2015; 19: 44-53.
[11] Szymczyk D, Horoch A. Implementacja elektronicznej dokumentacji medycznej. Część 2 – korzyści dla uczestników systemu ochrony zdrowia. Med Ogólna Nauk Zdr 2013; 19(3): 324-330.
[12] Szymczyk D, Horoch A. Implementacja elektronicznej dokumentacji medycznej. Część 1 – wpływ na efektywność pracy personelu medycznego. Med Ogólna Nauk Zdr 2013; 19(3): 319-323.
[13] Szymczyk D, Horoch A. Implementacja elektronicznej dokumentacji medycznej. Część 3 – szkolenie personelu medycznego w zakresie technicznego i prawnego użytkowania danych sensytywnych. Med Ogólna Nauk Zdr 2013; 19(3): 331-336.
[14] Latha N, Murthy B, Sunitha U.:Electronic Health Record. IJERT 2012; 1(10): 1-8.
[15] Romaszewski A, Trąbka W. Protection of personal data in health care entities and IT systems – the impact of new, national and EU legal regulations. Zesz Nauk WSZIB Krak 2015; 37: 1-14.
[16] Ustawa z dnia 5 września 2016 r. o usługach zaufania oraz identyfikacji elektronicznej (j.t. Dz. U. 2016 poz. 1579).
[17] Rzymowski J. Podpis elektroniczny i zasada równoważności w ustawie o podpisie elektronicznym i w EIDAS. Pieczęć elektroniczna. INNOWACJE 2016. ICT w służbie społeczeństwu 2016: 156-166.